REMARKS

Reconsideration of the rejections set forth in the Office Action mailed June 1, 2009, is respectfully requested. Claim 23 has been amended. Claims 23 and 72-78 remain pending in this case. The amendment to the specification is described in original Fig. 1. Support for the amendments to claim 23 can be found throughout the application; for example, at [0058], [0052] and Fig. 4B. Therefore, these amendments are made without introducing new matter.

Drawings

The drawings were objected to for including reference numbers not mentioned in the description. The specification has been amended to refer to reference number **51**. The applicant had previously submitted replacement figures on August 20, 2008. It is unclear if the replacement figures were entered. Therefore, please substitute replacement drawings attached herewith in the present application. These replacement figures correct "**80**" which should read "**90**." These objections should therefore be withdrawn.

Art Rejections

Claims 23, and 72-76 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Fleicshhacker et al (U.S. Patent Publication No. 2001/0021831) in view of Hundertmark et al (U.S. Patent Publication No. 2002/0077595). Claims 77-78 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Fleicshhacker in view of Hundertmark et al in further view of Jorgensen (U.S. Patent Publication No. 2003/0105426). Applicants respectfully traverse this rejection.

The claims, as amended, are directed to a catheter having a multilayer torque cable in the proximal region and require "a monolayer helical coil in the distal region of the elongate tubular

member, wherein the monolayer helical coil is an extension of the first helical coil [in the multilayer torque cable]." This feature allows for efficient torque transmission throughout the length of the catheter. The Office Action concedes that Fleicshhacker does not "teach or disclose a monolayer helical coil in the distal region of the elongate tubular member." The Office Action, however, relies on Fig. 8 of Hundertmark as an alleged teaching of a monolayer helical coil in the distal region of an elongate tubular member. Fleicshhacker and Hundertmark cannot properly be combined to make (1) a monolayer helical coil distal of a multilayer torque cable, or (2) a monolayer helical coil that is an extension of the first helical coil in the multilayer torque cable as required by amended claim 23. And such a feature would not be suggested by Hundertmark because in Hundertmark's coronary sinus procedure, torque transmission capabilities are not desired.

Hundertmark is directed to a coronary sinus catheter. The distal portion of the catheter is more flexible than the proximal portion to provide an atraumatic kink-resistant distal end. The flexible distal portion helps prevent damage to the coronary sinus and facilitates guiding the catheter into the coronary sinus. (Hundertmark at Abstract; [0007] [0023]) The distal portion of Hundertmark's catheter is preferably reinforced with an elongate member 48, preferably a wire, to provide *hoop* strength and *kink-resistance*. [0029] The softer coating 50 provides the catheter 2 with soft, pliable, atraumatic characteristics. [0031] By contrast to the Hundertmark catheter, the catheter of the instant invention requires a more rigid distal end and deflection tip in order to provide a guide wire with the support and orientation needed to cross a chronic total occlusion. (Petrick at [0006], [0048], [0061])

The Hundertmark coronary sinus catheter is designed to navigate a pre-existing lumen and does not need to, and is not designed to, provide support and orientation for a guide wire to cross an occlusion or penetrate a lesion. Hundertmark's coronary sinus catheter would not have sufficient support or rigidity to support a guide wire crossing a lesion, and the distal end would buckle if an attempt were made to use Hundertmark's catheter to support a guide wire crossing a lesion. Contrary to the Examiner's assertion, adding the more flexible end of Hundertmark to Fleicshhacker's device would not obtain the instant invention.

The Examiner states that a flexible end as that described by Hundertmark would be ideal for reaching a chronic total occlusion through the vasculature. However, the flexible end as described by Hundertmark would not provide the support needed to allow a guide wire to enter a lesion, to cross a chronic total occlusion. Applicant's invention, however, provides a catheter that has two coils in the deflection tip (numerals 14 and 15) that prevent the structure from longitudinally compressing. [0048]. The flexible end of Hundertmark is not able to provide the support that would allow a guide wire to cross an occlusion or penetrate a lesion.

Moreover, the coronary sinus catheter described in Hundertmark does not require torque capabilities to accomplish its function. In fact, torque capabilities add rigidity, which is to be avoided for Hundertmark atraumatic tip. The coronary sinus catheter is designed to enter the coronary sinus, occlude the coronary sinus, and to deliver fluid distal to the occluding member. [Abstract] There is no need for torque or any type of rotation. Hence, although Hundertmark and Fleischhacker can be *broadly* described as related (dealing with medical devices and catheters) the two are unrelated as to purpose and required characteristics. For example, coil 48

of Hundertmark is provided to supply hoop strength and kink-resistance, whereas the double coil structure of Fleischhacker is designed to provide high torque transfer.

There would have been no reason to combine a flexible-tip device designed to enter the coronary sinus (where there is no need for rotation or to help push through anything and where maximum flexibility is required to avoid causing tissue damage) with a high torque transfer device, other than impermissible hindsight. Further, even if combined, Hundertmark and Fleischhacker still do not reach the instant invention because neither teaches a monolayer helical coil in the distal region of the elongate tubular member, where the monolayer helical coil is an extension of the first helical coil in the multilayer torque cable.

Claim 23 is therefore patentably distinct from the cited art. Each of claims 72-78 is dependent on claim 23 and therefore claims 72-78 are patentably distinct from the cited art for the same reasons applicable to claim 23. The rejections over Fleicshhacker and Hundertmark should therefore be withdrawn.

CONCLUSION

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,
O'MELVENY & MYERS LLP

Dated: August 3, 2009

By: 
John Kappos
Reg. No. 37,861
Attorneys for Applicants

O'Melveny & Myers LLP
610 Newport Center Drive, 17th Floor
Newport Beach, CA 92660-6429